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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,588	05/03/2001	Stephen Friend	215538.00108	7335

27160 7590 04/08/2003

PATENT ADMINSTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 WEST MONROE STREET
SUITE 1600
CHICAGO, IL 60661-3693

EXAMINER	
LEFFERS JR, GERALD G	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/847,588	Applicant(s) FRIEND ET AL.	
	Examiner Gerald G Leffers Jr.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with th c rrespondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2003* .

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *21-22, 26-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-20, 23-25 drawn to the p53 gene as the gene comprising a primary genetic defect) in Paper No. 10, filed 1/28/03, is acknowledged. The traversal is on the ground(s) that 1) the fact that claim 1 is a linking claim indicates that a search of all of the independent embodiments together would not be burdensome, 2) the only art that would be relevant to the claimed invention is that published within 10 years prior to the effective filing date of the instant application, and 3) the examiner has made no showing of a burdensome search requirement for examining all of the recited primary mutations together. This is not found persuasive because the response ignores the fact that each of the primary defects is directed to a unique protein, each having distinct structural/functional characteristics and whose operation in the cell has different effects such that practicing the claimed method will necessarily identify different types of secondary lethal gene products as potential drug targets. As such, the non-patent literature search required for examining each of the different primary gene defects is going to be different. For at least these reasons, there is a burdensome search requirement in searching each of the different primary defects together.

The argument regarding the time period in which prior art will be available for searching is not supported and is not persuasive in any case. This appears to be an argument that not much in the way of applicable art would have been published in the ten years prior to the effective filing date. In the period from 11/87 to 11/97, an enormous amount of research has been done in the biotechnological fields that has been published, all of which would have to be sifted to identify relevant prior art. Therefore, applicants' argument along these lines is not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement filed 4/15/02 as Paper No. 5 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office (e.g. PTO Form 1449). Although Paper No. 5 indicates that a PTO Form 1449 was filed with the references, no such form is present in the file. It has been placed in the application file, but the information referred to therein has not been considered. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Objections

Claims 1-20, 23-25 are objected to because of the following informalities: the claims are drawn to nonelected embodiments of the claimed invention (i.e. primary defects in genes other than the p53 gene). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20, 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "determining the gene product of said lethal secondary site to provide a secondary drug target" are unclear. The phrase "of said lethal secondary site" implies that the secondary lethal site is necessarily within a coding sequence for a particular gene product. The secondary lethal mutation could as well be located within the regulatory regions of a gene (e.g. within an promoter/enhancer region). It would be remedial to amend the claim language to more clearly indicate whether the secondary lethal site is necessarily located within the coding region of a gene.

Claim 2 is vague and indefinite in that the metes and bounds of the phrase "found in or associated with a human tumor". It is unclear how a gene defect can be "associated with" a human tumor and not actually found in the human tumor.

Claim 3 is vague and indefinite in that the metes and bounds of the phrase "analogous or homologous to a defect found in or associated with a human tumor" are unclear. The term "associated with" a human tumor is indefinite for reasons given above. It is also unclear the degree of sequence identity or functional similarity required for a gene defect to be "analogous" or "homologous" to another gene defect found in human tumors.

Claims 10-11, 14 and 24are vague and indefinite in that they specify that the secondary gene defect identified by the claimed method is in particular genes. Since the claimed methods are directed towards the identification of secondary genetic defects, what then is the point of performing the steps recited in the claims if the site of the secondary genetic defect is already

known? Is there some missing step to be performed in these particular claims that would go beyond identification of the site of the secondary mutation?

Claim 12 is vague and indefinite in that the metes and bounds of the terms mammalian "analog" or "homolog" are unclear. These terms are not clearly defined in the specification and are open to interpretation by the individual practitioner.

Claim 18 is vague and indefinite in that the metes and bounds of the term "genetically tractable organism" are unclear. The term does not appear to be clearly defined in the specification and is open to interpretation by the individual practitioner.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
April 7, 2003